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| APPLICATION NO.,  | FILING DATE       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/706,420  | 11/12/2003        | Robert Murray        | 006943.00349        | 6802             |
| 66811 7590 11/01/2007 BANNER & WITCOFF, LTD. and ATTORNEYS FOR CLIENT NO. 006943 10 SOUTH WACKER DR. SUITE 3000 |                   |                      | EXAMINER            |                  |
|   |                   |                      | PRATT, HELEN F      |                  |
|   |                   |                      | ART UNIT            | PAPER NUMBER     |
|   | CHICAGO, IL 60606 |                      | 1794                |                  |
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|   |                   |                      | 11/01/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)  |  |  |  |
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| Office Action Summary  | 10/706,420   | MURRAY ET AL.   |  |  |  |
| Onice Action Summary   | Examiner   | Art Unit  |  |  |  |
|  | Helen F. Pratt   | 1794  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNION 36(a). In no event, however, may a will apply and will expire SIX (6) MONO, cause the application to become AF | CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). |  |  |  |
| Status   |  | •   |  |  |  |
| <ol> <li>Responsive to communication(s) filed on <u>9-</u>.</li> <li>This action is <b>FINAL</b>.</li> <li>Since this application is in condition for alloward closed in accordance with the practice under <u>B</u>.</li> </ol>   | •  | · •   |  |  |  |
|  | zx parte Quayle, 1999 O.L  | 7. 11, <del>4</del> 00 0.0. 210.  |  |  |  |
| Disposition of Claims  |  |   |  |  |  |
| 4) ⊠ Claim(s) <u>185-212</u> is/are pending in the applicated 4a) Of the above claim(s) is/are withdrated 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>185-212</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or  | wn from consideration.   |   |  |  |  |
| Application Papers   |  |   |  |  |  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 10.  | epted or b) objected to drawing(s) be held in abeyar tion is required if the drawing   | nce. See 37 CFR 1.85(a).<br>(s) is objected to. See 37 CFR 1.121(d).  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority document</li> <li>2. Certified copies of the priority document</li> <li>3. Copies of the certified copies of the priority application from the International Burea</li> <li>* See the attached detailed Office action for a list</li> </ul>   | s have been received. Is have been received in A rity documents have been u (PCT Rule 17.2(a)).                                      | opplication No<br>received in this National Stage   |  |  |  |
| Attachment(s)  |  |   |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li></ol>  | Paper No(  | Summary (PTO-413)<br>s)/Mail Date<br>nformal Patent Application<br>   |  |  |  |

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 185-212 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Auzerie (FR 2770778 A1) in view of Howard et al. (5,968,544) and Kuznicki et al. (5,681,569) and further in view of Greenleaf (5,447,730) and further in view of Howard, 4,237,118, Mathewson US 2005/0095271 A1, Armonti et al. 7,001,612, and Mattson et al. (2002/0132214 A1).

Auzerie discloses a rehydration solution composition as in claim 185 containing 20-75 meq chloride, from 0-50 meq potassium, and 40-75 meq of sodium. The composition contains water since it is a solution. The osmolality is from 150-350

m.osml. (abstract and page 2, lines 15-24). Claim 185 differs from the reference in the use of 3 types of carbohydrates .

Sucrose and glucose are disclosed as in claim 185 (abstract). Howard et al. disclose that it is known to use starch and sugars in a composition containing electrolytes, flavors, coloring agents and clouding (col. 3, lines 55-60, col. 4, lines 5-22), also, claim 199. Kuznicki et al. disclose a beverage containing electrolytes and carbohydrates (abstract and col. 6, lines 10-15). The carbohydrates can be sucrose, corn syrup, high fructose corn syrup and sugar. Nothing critical is seen in the specification as to using three types of carbohydrates (claim 188) or particular amounts as the osmolarity has been disclosed above. The particular amount is seen as being within the skill of the ordinary worker as in claims 189-195. Sucrose is a disaccharide and fructose is a monosaccharide. Both these types of sugars are duplicated in applicants list of carbohydrates and nothing new is seen in the use of other carbohydrates since mono and disaccharides have been disclosed by Auzerie. Therefore, it would have been obvious to use three known carbohydrates in the composition of Auzerie for their known functions particularly since no unexpected results have been shown as to using two carbohydrates instead of three.

Claims 185 and 212 further require that fructose is one of the carbohydrate sources and that the amount of fructose is less than the amount of glucose. However, Greenleaf discloses a beverage with all sources containing glucose in higher amounts than fructose. The maltodextrin is considered to be a source of glucose. No criticality or anything unobvious is seen in using less fructose than glucose. Also, Auzerie

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discloses the use of 16 g. of glucose and 20 g. of saccharose (sucrose). Since saccharose is made of glucose and fructose, in amounts of 50% each, then saccharose would have had 10 g. of fructose which is less than the amount of glucose as claimed (page 4, lines 1-10). It is known that chloride produces a bitter taste, as in the use of calcium chloride in beverages, is limited due to the bitter taste. It would have been obvious to limit the amount of chloride due to its bitterness. Also, a lower amount of salt would automatically produce a lesser amount of chloride, and as above it is known to limit the amount of sodium and salt in beverages and food products. Therefore, it would have been obvious to use fructose in lesser amounts as shown by Greenleaf et al. in the composition of the combined references and to use lesser amount of fructose as shown by Auzerie.

Claims 185 and 212 further require particular amounts of sodium and chloride, which are more narrow ranges than previously claimed. However, the references show amounts within the claimed range or near it. Also, Howard discloses that it is known to use at least 182 mg of sodium (abstract). The reference discloses that 920 mg is a fairly moderate level so as to avoid fluid retention, para. (37). Armonti et al. disclose 0.3 to .7 g/liter is disclosed in a liquid composition. Mathewson disclose that it is known to promote fluid retention during exercise by using sodium in amount of 0.4 to 1.2 parts of sodium to 100 parts of carbohydrates (abstract). Also, 0.5-0.7 g/l of sodium is recombined for exercise lasting longer than 1 hour (0014). These amounts are within the claimed amounts for sodium. Mattson et al. disclose that the effects of too much sodium are well known (0416).

Therefore, it would have been obvious to use lesser amounts of sodium as shown by the added references in the composition of Auzerie if rehydration was a particular concern.

Claims 196-198 further require particular amounts of electrolytes. However, the amounts of the references are within or near the claimed amounts. As the claimed osmolality has been shown, it would have been within the skill of the ordinary worker to vary the amounts of electrolytes to achieve the required osmolality. Therefore, it would have been obvious to use particular amounts of electrolytes to achieve a particular osmolality.

The particular amounts of carbohydrate are disclosed as in claims 186-187 by the reference to Auzerie, since the osmolality has been shown, and the claimed amounts of ions as in steps b and c which are sodium and chloride as in claims 196-198 or amounts which are almost in the claimed range as is the chloride of 20-75meq (abstract).

The beverage composition of the combined references is seen to promote fluid retention and stimulate voluntary fluid consumption since the composition has been shown.

Claim 211 is to a concentrate. The concentrate would have to contain water, if it is in solution form. Nothing new is seen in the use of a concentrate, which is merely the same composition with less water. Therefore, it would have been obvious to make a

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concentrate especially since no amount of water is cited in the abstract of Auzerie, making it possible to add various amounts of water to achieve the particular osmolality.

Various amounts of calcium and magnesium, are disclosed as in claims 199-205 as in Howard et al. (col. 4, lines 11-22). No amounts of flavoring agent are required in claims 206-208. These are well known ingredients common in the use of beverages. The use of particular amounts is seen as being within the skill of the ordinary worker. Howard et al. disclose that it is known to add minerals in amounts to provide the correct osmolarity. Therefore, it would have been obvious to use additional electrolytes in the composition of Auzerie for their known function and to give the correct osmolarity.

Claims 206 to 209 further require a flavoring agent and a clouding agent.

Howard et al. as above discloses such. Particular amounts are seen as being within the skill of the ordinary worker. Therefore, it would have been obvious to use known flavoring agents and clouding agents in particular amounts for their known function in the composition of Auzerie (FR 2770778 A1).

Claim 212 further requires various amounts of ingredients, which have been disclosed above. The particular amount of fluid retention is seen to have been about the same since the osmolality has been shown. The discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). In developing a beverage product, properties such as osmolality and taste are important. It appears that the precise ingredients as well as their proportions affect the osmolality of the product, and thus are result effective variables, which one of ordinary skill in the art would routinely optimize.

Therefore, it would have been obvious to use various amounts as disclosed by the combined references.

Claim 210 is rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to the above claims, and further in view of Hutt et al. (6,730,337).

Claim 210 further requires particular amounts of citric acid. Hutt et al. discloses that it is known to use citric acid, calcium in a beverage that has an osmolality at within the claimed osmolality (abstract and col. 2, lines col. 2, lines 17-25, col. 4, lines 15-30). Therefore, it would have been obvious to use known ingredients such as citric acid for its known function of adding acidity in the composition of the combined references.

## **ARGUMENTS**

Applicant's arguments filed 9-25-07 have been fully considered but they are not persuasive. Applicants argue that Auzeria does not disclose the claimed amounts of sodium and chloride. However, the claimed amounts of sodium are shown, and near amounts of chloride at the lower end. References have been added to show that it is known to limit the amount of sodium. It is known that chloride produces a bitter taste, and it would have been obvious to limit the amount of chloride to produce an acceptable product. The amount taste of the food product is within the skill of the ordinary worker to vary, since of course no one wants a very salty beverage, and as above, it is known to limit the amount of sodium.

It is not seen that it was not known to use lower amounts of sodium and chloride ions as shown by the above references. Certainly the amount of salt and fluid

retentions can be correlated. No limitations as to improvement of voluntary fluid consumption are seen.

Applicants also, have disclosed in their prior art that it is known that research has indicated that sodium content in fluid replacement beverages has a marked effect on fluid retention after exercise and that 40-100 milliequivalents/liter increase fluid retention and maintain a positive fluid balance (0006 of specification). Applicants also disclose that the two major physiological drivers behind voluntary draining are plasma osmolality and plasma volume and these are known factors (0007). Even "ingesting too high a level of sodium causes rapid restoration of plasma volume, which reduces the drinking response and prevents adequate rehydration....the sensory properties of beverages containing too high a level of sodium are unfavorable, and would further reduce the drive to drink" (0007). Certainly, knowing these factors, would make one be careful of how much salt or sodium was added to a composition.

Applicants argue that the reference to Howard was used to show the 3 types of carbohydrates and not disclose the whole invention.

Kuzicki was used to show also the use of carbohydrates, and to show the use of maltodextrin as a source of glucose and Hutt to disclose the use of citric acid in beverages.

The motivation to combine is in the office action. Each reference can be used for what it teaches.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Keith Hendricks, can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Hp 10-29-07

HELEN PRATT
PRIMARY EXAMINER